REMARKS/ARGUMENTS

Claims 1-36 are pending in the present application. In the Office Action, claims 2 and 23-36 were withdrawn and claims 1 and 3-22 were rejected. In response to the Office Action, claims 23-36 have been cancelled and claims 1, 11, 12 and 22 have been amended. New claims 37-42 have been added. No new matter has been added. Reexamination and reconsideration of the pending claims is respectfully requested.

Election/Restrictions

Applicants acknowledge the withdrawal of claims 2 and 23-36.

Priority

In the Office Action, the Examiner indicated that the disclosure of prior filed Application No. 10/637,713 failed to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of the present application. The Examiner therefore indicated that the effective filing date for purposes of applying prior to the present application will be the filing date of the present application, March 30, 2004. Applicants respectfully request reconsideration of the effective filing date of the present application.

Claim 1 of the present application currently recites:

1. (Currently Amended) A method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising:

positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon;

radially expanding the expandable member thereby radially expanding a first stent in the main branch;

positioning the delivery catheter in the side branch; and

radially expanding the expandable member thereby radially expanding a second stent in the side branch;

wherein the delivery catheter is not removed from the vessel between deploying the first and second stents.

The Examiner acknowledged that parent Application No. 10/637,713 discloses a multiple stent delivery device. Additionally, parent Application No. 10/637,713 also discloses the following:

> [0100] As an additional feature, circumferential slots 104 provide a pathway through which vessel side branches can be accessed for catheter interventions. Should stent segment 32 be deployed at a location in which it covers the ostium of a side branch to which access is desired, a balloon dilatation catheter may be positioned through circumferential slot 104 and expanded. This deforms circumferential struts 109, 111 axially outward, thereby expanding circumferential slot 104 and further expanding upper and lower slots 102, as shown in phantom in Fig. 3B. This provides a relatively large opening 120 through which a catheter may be inserted through stent segment 32 and into the side branch for placing stents, performing angioplasty, or carrying out other interventions.

Moreover, parent Application No. 10/637,713 also discloses the following:

> [0104] It should also be noted that the embodiment of Figs. 6A-6B retains the feature described above with respect to Figs. 5A-5B to enable access to vessel side branches blocked by stent segment 32. Should such side branch access be desired, a dilatation catheter may be inserted into circumferential slot 128 and expanded to provide an enlarged opening through which a side branch may be entered.

Therefore, Applicants maintain that the disclosure in paragraphs [0100] and [0104] of Application No. 10/637,713 is adequate to satisfy the requirements of 35 U.S.C. § 112 to one of ordinary skill in the art in support of at least claim 1 of the present application. Thus, the effective filing date of the present application should be at least the filing date of Application No. 10/637,713 which was filed on August 8, 2003. Applicants respectfully request that the effective filing date of the present application be changed to at least August 8, 2003.

Claim Rejections - 35 U.S.C. § 102

In the Office Action, claims 1, 3-13 and 17-22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brucker et al. (U.S. Patent Publication No. 2002/0193873). Such rejection is overcome for at least the following reasons.

Claim 1 has been amended to recite in part the steps of positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon; radially expanding the expandable member thereby radially expanding a first stent in the main branch; ... and radially expanding the expandable member thereby radially expanding a second stent in the side branch. Support for this amendment may be found in Figs. 7A-7E, therefore no new matter has been added. The cited reference fails to teach or suggest each and every element of the claimed invention.

Brucker discloses systems for delivering a bifurcated stent to a bifurcation site (Abstract). The embodiment seen in Figs. 18-20 discloses a delivery catheter carrying two stents, each of which is mounted on a separate balloon. A first stent is deployed into one branch of the bifurcation by expanding a first balloon. The delivery catheter is repositioned and the second stent is deployed into the other branch of the bifurcation by expanding the second balloon. Because two separate balloons are required to deploy the two stents, Brucker fails to teach or suggest using the same balloon to expand both stents into their respective branches of the bifurcation, as required by claim 1 which now recites the steps of radially expanding the expandable member thereby radially expanding a first stent in the main branch; ... and radially expanding the expandable member thereby radially expanding a second stent in the side branch.

Because a single reference fails to disclose, teach or suggest each and every element of the claimed invention, anticipation cannot be established under 35 U.S.C. § 102(b). Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claim 1 and the claims depending therefrom.

Independent claim 12 has similarly been amended as claim 1 above, therefore for at least the same reasons discussed, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection of claim 12 and the claims depending therefrom.

Claims 11 and 22 have been amended to recite in part dilating at least one lesion in the vessel using an expandable member on the delivery catheter without a stent disposed thereon before deploying at least one of the first and second stents. Support for this amendment may be found in paragraphs 0060 and 0056 of the application as filed, therefore no new matter has been added. As noted in the Office Action (page 5), in Brucker when the first stent is deployed it dilates at least one lesion before the second stent is deployed. However, claims 11 and 22 as amended now recite in part dilating at least one lesion in the vessel using an expandable member on the delivery catheter without a stent disposed thereon. Because lesion dilation only occurs in Brucker when a stent is disposed on the balloon, Brucker fails to anticipate claims 11 and 22.

Claim Rejections 35 U.S.C. § 103

Claims 14-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brucker in view of Loos et al. (U.S. Patent No. 6,579,309). Such rejection is overcome for at least the following reasons.

Claims 14-16 include the steps recited in independent claim 12. Claim 12 has been amended to recite in part the steps of positioning a delivery catheter in the first branch, the delivery catheter having an expandable member disposed thereon; radially expanding the expandable member thereby radially expanding a first stent in the first branch, a portion of the first stent being disposed across the bifurcation; ... and radially expanding the expandable member thereby radially expanding a second stent, at least a portion of the second stent being disposed in the second branch. Support for this amendment has previously been discussed. Neither Brucker or Loos teach or suggest each and every element of the claimed invention.

Brucker has already been distinguished from claim 12 as discussed above because Brucker discloses using two different balloons to deploy two stents into the bifurcation, not the same balloon as in claim 12. Loos fails to provide the elements missing from Brucker. Loos discloses a stent for implantation in the region of vessel branchings (Abstract). Loos also discloses using a single balloon having two expandable regions to deploy a single stent into the main branch (see Fig. 1) and then support elements are pivoted into the branching portion of the

vessel (Abstract). Thus, there is only a single stent deployed by a single balloon into the vessel and Loos fails to teach or suggest radially expanding the expandable member thereby radially expanding a first stent in the first branch, a portion of the first stent being disposed across the bifurcation; ... and radially expanding the expandable member thereby radially expanding a second stent, at least a portion of the second stent being disposed in the second branch, as required by claims 14-16.

Additionally, one of ordinary skill in the art would not combine Loos' stent with Brucker's delivery device and method as suggested by the Examiner because the resulting device would be inoperative. Loos' stent is expanded by inflation of two mutually separate chambers on a single balloon (col. 6, line 62 - col. 7, line 10). After expansion of the stent, the support elements are pivoted into the side branch by means of a guidewire used to plastically deform the support elements radially outward (col. 7, lines 11-17). Thus, a guidewire exit port must be disposed between the two separate balloon chambers in order to pivot the support elements outward (see item 17 in Fig.1). Even if Loos' stent was mounted onto both balloons in Brucker's delivery device, Brucker fails to teach or suggest a guidewire exit port between the two balloons. Brucker only discloses a guidewire exit port at the distal tip of the delivery catheter. Therefore, it would not be possible to radially expand the Loos' support elements into a side branch. Furthermore, Brucker teaches inflating each balloon separately while proper expansion of Loos' stent would require both balloons to be inflated simultaneously. Thus, use of Loos' stent with Brucker's delivery catheter and method would require reconstruction and redesign of elements in Brucker (moving the guidewire exit port) as well as a change in the basic principle under which the construction of Brucker's delivery catheter was designed to operate (order of balloon inflation). Because this changes the principle of operation of the cited reference, the teachings of Brucker are not sufficient to establish *prima facie* obviousness. M.P.E.P. § 2143.01 VI.

Because the cited references alone or in combination fail to teach each and every element of the claimed invention and because the resulting combination would be inoperative, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 14-16.

New Claims

Claims 37-42 have been added. Support for these claims may be found *inter alia* in paragraphs 0037, 0040 of the application as filed, therefore no new matter has been added. Claims 37-42 are believed to be patentable because they recite the steps of selecting a first number of the separable segments for radial expansion ... and selecting a second number of the separable segments for radial expansion ... wherein the first number of segments is different than the second number. Brucker only discloses a single stent in each branch of the bifurcation, thus Brucker fails to teach or suggest selecting a first number of segments ... and selecting a second number of segments ... wherein the first number of segments is different than the second number, as required by claims 37-42. Similarly, Loos only discloses deploying a single stent on one branch, therefore Loos also fails to teach or suggest these steps.

Related Cases

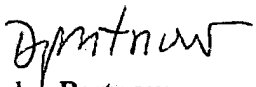
As a final matter, a Supplemental IDS will be submitted for consideration by the Examiner during prosecution of this application. Included in the Supplemental IDS is a listing of commonly-owned related cases. Each of these cases include disclosure related to prostheses and prostheses delivery systems. Applicants assume that the Examiner can access these but would be happy to provide copies of prosecution documents if requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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